2006-01-01

The Tromped, an In-Flight Exercise Device to Prevent Flight Related Deep Vein Thrombosis

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Recommended Citation

Collins, C., Kennedy, D., Jerrams, S., Corrigan, T.: The Tromped, an in-flight exercise device to prevent Flight Related Deep Vein Thrombosis, ICRAT Proceedings, Bulgaria, Summer 2006.

The Tromped, a solution for flight related Deep Vein Thrombosis

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Abstract.

Medical and Engineering research studies have shown the potential risks of long haul flight travel and methods of preventing it occurring. The risk of serious health problems or even death is known to arise from lack of venous movement and increased coagulation (clotting) of the blood. These factors contribute to the development of deep vein thrombosis (DVT) and this is more likely to occur in situations where people are seated for long periods during travel on land or in air. Currently long haul airlines have yet to be seen to introduce physical preventative measures against this syndrome.
A prototype design of an in-flight exercise machine to prevent flight related deep vein thrombosis (FRDVT) has been developed. The prototype is an exercise device consisting of a foot pedal attached to a base by a hinge mechanism and is made from aircraft grade aluminium alloy material. Mechanical testing and medical experiments were conducted on a number of volunteers at the Faculty of Engineering, Dublin Institute of Technology and at Beaumont Hospital, Dublin, respectively to confirm the design characteristics of the device. Test results have indicated that the use of such a device can increase blood circulation in critical areas of the lower body limbs and prevent the occurrence of DVT and this paper discusses the threat that DVT holds to both travellers and people prone to periods of immobility.

Keywords: Deep vein Thrombosis, Pulmonary embolus, Air Plethsymograph

1.0. Introduction.

Deep Vein Thrombosis (DVT) is a disorder which affects mainly the deep veins of the lower limbs and thighs of humans. This research was aimed at developing an in-flight exercise machine to prevent this occurring in passengers at risk to this disorder. A thrombus is a blood clot that forms in the vessels of the lower limbs and thighs and remains there blocking the flow of blood as shown in Figure 1. Venous thrombi are red and contain many red blood cells, which are entrapped in a fibrin network. (Fibrin is an insoluble protein essential to clotting of the blood) [1].
According to a study carried out in 1952, by Wright HP and Osborne SB [2], on the effects of posture on venous velocity, sitting in one position reduces the venous blood flow velocity by 66%. The study "Prophylaxis of Venous Thromboembolism: An overview" states *"Pulmonary embolism originates in the deep veins of the legs in 90 percent or more of cases*" [3] The Lonflit 2 study demonstrated that 85 per cent of DVT occluded in non-aisle passengers [4]
Inherent risk factors such as anti-thrombin III, Protein C deficiency, Protein S deficiency, factor V Leiden mutation and acquired risk factors such as surgery, cancer and oral contraceptives, to name but a few are known to increase the risk of DVT [5]. A major problem of DVT is that 80% of PE occurs without signs, with 66% of deaths occurring within 30 minutes [6]. When people develop PE unexpectedly it may be due to an asymptomatic thrombus (one without signs or symptoms) travelling into pulmonary vessels, which causes the onset of cardiogenic shock, followed by

circulatory failure and consequently death. [7]. *"Pulmonary embolism (PE) remains a common cause of mortality and its diagnosis is missed in up to 71% of instances"* [8]. According to Ferrari et al., 1999, [9] PE may develop in passengers several weeks post travel. This would be due to the fact that some DVT may be asymptomatic showing no symptoms. As a result many people may be dying directly from flight related DVT and yet this reason may never be attributed to their cause of death.
A Study conducted by Caillard and Clerel, [10] at the Aeroports de Paris emergency unit from the year 1990-2000, revealed that of 109 patients diagnosed with symptomatic pulmonary thromboembolus (PTE) 83 were female and 24 were male. The mean age was 57.3 yrs. The annual incidence of venous thromboembolism (VTE) has been estimated at 1.6-1.8 per 1000 [11]. These figures are very worrying considering The IATA Environmental Review 2004, stated that the international airlines between them carried 1.6 billion passengers [12].
Therefore, as a result of the dangers of FRDVT, a prototype design, referred to as "The Tromped", was developed to prevent this syndrome. The Tromped requires the user to compress two foot pumps, thus activating venous return in the lower limbs, Figure 5.1. Muscle contraction is the main activator of the venous pump system. In the back of the human calf are the two main venous pumps, namely the Gastrocnemius muscle and the soleus muscle, [13] which will be the main muscles activated during use of the Tromped. Some medical experts also believe that the reduction in the partial pressure of oxygen experienced on aircraft in flight also contributes to the development of thrombus formation. The Tromped prototype is currently undergoing modifications, so that the final commercial product will be incorporated into aircraft design. Airlines have not as yet, acknowledged responsibility for this medical condition, primarily due to wording of the Warsaw Convention, [14] which determines compensation packages paid to passengers. The article "Flights triple blood clot risks" [15] states that a World Health Organisation report into flight related DVT, which is to be published in Spring 2005, has found
"a flight of more than four hours increases the risk of deep vein thrombosis in the general population by between three and five times."

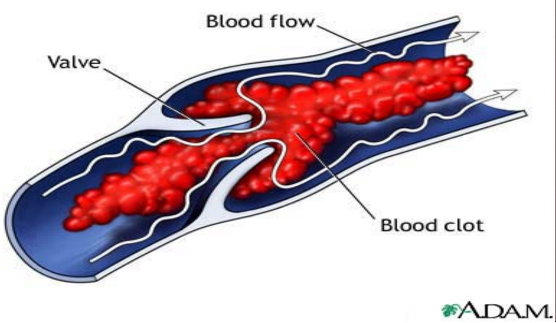

Figure 1.1. Venous Blood Clot [16].

Figure 1.2. DVT in the groin area [17].

2.0. Calf muscle pump function.
Contraction of the calf muscles results in an ejection volume of venous flow towards the heart. Stasis will occur due to immobility as the blood pools in the veins, which become dilated due to prolonged rest.
During normal movement the three venous pumps which are the foot pump, the proximal pump and the distal calf pump operate in the following manner. Before the foot bears any weight, the ankle is dorsiflexed, emptying the distal calf pump. This

action will occur when the passenger places his/her foot on the uncompressed Tromped pedal. By pressing down on the pedal the user will empty the foot pump with the corresponding flexing of the plantar area of the foot emptying the proximal calf pump into the popliteal and femoral veins. The popliteal vein is found behind the knee area and the femoral vein extends up into the thigh area. Both the Gastrocnemius and the Soleus muscles are the muscles used to produce this movement, thus preventing venous stasis.
The venous valves in the deep and superficial veins prevent the reflux of blood against the normal direction of venous flow. If and when these valves collapse or fail, varicose veins may develop. The main problem associated with varicose veins is that the blood tends to pool at the bottom of the vein and remain there [18, 19].

There are two general means of prophylaxis, which include mechanical methods and pharmacological agents. Mechanical methods unlike pharmacological prophylaxis do not increase the risk of bleeding. Devices such as the Novamedix A-V Impulse System [22] and Medi Vein Compression Stockings, work by mimicking the natural physiological processes that ensure blood circulation in the legs and arm.
If *"routine prophylaxis reduces morbidity, mortality and costs in hospitalised patients at risk of DVT and PE",*[7] surely it should also be used for passengers on board aircraft and other forms of transport, at risk of this same syndrome?
Leading experts in the field of PE believe that simply treating symptoms when they present themselves should be avoided by ensuring the illness does not occur in the first place. This form of thinking should be applied by the airlines, which should set out to perform a duty of care to their passengers by providing a means of prophylaxis on board their flights.
"… the application of prophylactic measures is much more effective for preventing death and morbidity from pulmonary embolism than is treatment of the established event" [3].

3.0 Normal Operation of the Aircraft.
Aircraft generally fly at an altitude of 35,000 to 40,000 feet. The atmospheric pressure (atm) experienced at this altitude is 2.73 psi. The interior of the aircraft will experience an atm equivalent to an altitude of 8000 feet, which is 10.91 psi, so in effect there is a pressure differential of 8.18 psi, between the interior and the exterior of the aircraft cabin [21]. Aircraft are not pressurised to replicate atmospheric conditions at sea level, when flying at high altitudes, such as 40,000 feet as the aircraft structure would not be able to survive with the huge difference in pressures, inside and outside it. [21, 22]. The ambient pressure at 40,000 feet is 140mmHg or 18.7kPa, which would be insufficient to allow ease of breathing in passengers. Therefore the interior cabin pressure experienced by passengers is the equivalent of an altitude between 5000 and 8000 feet above sea level. These low ambient cabin pressures result in a reduction of the partial pressure of oxygen ($P0_2$) and the arterial pressure of oxygen (PaO_2) available to passengers even though the concentration of oxygen (at 21 per cent) remains as normal [22].

	Ambient Pressure	Partial pressure of oxygen (PO_2)	Arterial Pressure of Oxygen
Sea Level	760 mmHg	149 mmHg	94mmHg
8,000 feet	565 mmHg	109 mmHg	55mmHg.
40,00 feet	140 mmHg		

Table 3.1. Pressure/Altitude values.

What this means exactly is that passengers experience approximately 90 per cent blood oxygen saturation. In a sense passengers are experiencing hypoxia due to the reduction in oxygen available to the blood. However the majority of passengers can carry on as normal with exception to passengers suffering with anaemia, pulmonary, and coronary diseases [23].

High altitude has the following repercussions on the human body:

i. There is a decrease in the driving pressure for oxygen from the air to the blood
ii. there is *"a lower affinity of haemoglobin for oxygen",*
iii. the high altitude creates a limitation on the diffusion of oxygen from the air to the blood [24]

With in a few hours of climbing to a higher altitude, there is a 10-20 per cent reduction in plasma volume (plasma is the yellow-grey protein containing fluid portion of the blood, in which blood cells and platelets are suspended in). With a reduction of plasma volume there is a resulting increase in haemoglobin concentration with increase in red cell numbers. Basically what this means is that there are too many red cells and not enough oxygen available for them, which can lead to the development of venous thrombi [25].

4.0. Legal repercussions of FRDVT

The "Convention for the Unification of Certain Rules relating to International Carraige by Air" signed at Warsaw in 1929 , states in Article 17 *"The carrier is liable for damage sustained in the event of the death or wounding of a passenger or any other bodily injury suffered by a passenger, if the <u>accident</u> which caused the damage so sustained took place on board the aircraft or in the course of any of the operations of embarking or disembarking"* [14].

Sufferers of flight related DVT have claimed that the development of DVT and the failure of airlines to warn of this travel related syndrome should be classed as an accident, under the Warsaw Convention, thus enabling them to claim compensation under the carrier's liability acts. In spite of this, Courts of differing levels have taken the term "accident" to have an altogether different meaning. The case Australian Casualty Co. Ltd v Federico defined an accident as: *"It is something which happens without intention or design. When used with reference to something which causes injury, it means an unexpected and unintended mishap"* [26].

Yet again a differing interpretation of the term "accident" in the *Air France v Saks case* "*We conclude that liability under article 17 of the Warsaw Convention arises only if a passenger's injury is caused by an unexpected or unusual event or happening that is EXTERNAL to the passenger"* [27].

It appears with many if not all DVT legal cases that the court requires proof of an unusual or unexpected event occurring on the flight in question.

An interesting twist to the DVT battle between sufferers of DVT and the airlines occurred when British Airways PLC came to the decision to waive their right to legal costs if the Courts find in favour of them [28]. This is a very clever customer relation's decision, yet some may feel that this in itself is the first step of the airlines admitting responsibility for the syndrome.

Simply developing a DVT and being treated successfully is not the end of the problem *"A history of DVT increases the risk of chronic venous insufficiency 25.7 – fold, compared with those without a history of DVT"* [29].

Do airlines want to accept responsibility for life long illness of their customers or do they want to be seen to take proactive action by providing a means of prophylaxis for their passengers, as a duty of care?

5.0. The Tromped prototype.

The prototype was produced from Aluminium alloy of aircraft type grade. The prototype consists of a foot pedal, attached to a base by means of a compression spring at the upper end of the pedal and a hinge at the lower end of the pedal. Compression springs of differing tensions were obtained. To determine if any of the springs would produce the required ejection volume of blood, four test jigs were produced and labelled Test Jig 1, 2, 3 and 4 to distinguish them for the medical experiment.

Both Test Jig 2 and 3 produced an ejection volume fraction of greater than the required 60%. Subsequently the spring used in Test Jig 3 was tested to determine its compression value, as it was found to be the spring most user friendly by the ten volunteers. It is with this compression value that the Tromped prototype is being redesigned and developed, for use on board commercial aircraft.

Figure 5.1. Revised Tromped prototype.

Figure 5.2. Revised Test Jigs

6.0. Medical Experiment conducted to test the efficacy of the Tromped.

A sample of ten volunteers, were recruited to test the efficiency of the Tromped Test Jigs in preventing DVT. An Air Plethysmograph machine, as shown in Figure 6.1, was used in the Non-Invasive Vascular Lab in Beaumont Hospital, Dublin. Air Plethysmography has been used to study relative volume changes in the lower limbs in response to postural alterations and muscular exercise [30]. Six males and four females completed the medical exam, with the volunteers ranging in age from 20 to 69 years. The volunteers were placed in the supine position (lying flat on their back) with a calibrated air chamber placed around the calf of their right leg. The air chamber was inflated to 7mmHg (to make contact with the limb) and connected to the Air Plethysmograph, which contains a Pressure Transducer, amplifier and a pen recorder. The leg was then elevated at an angle of 45° so as to empty the veins of blood. When a stable baseline is recorded on the graph the patient was then requested to stand up vertically, with all their weight on their left leg. An increase in Venous Volume (VV) was then recorded on the graph as a result in venous filling, 100 – 150 ml in normal limbs. The venous filling index (VFI), a measure of the average filling rate (ml/sec) is calculated from equation (1).

$$VFI = 90\%VV / (VFT \times 90) \qquad \textbf{(1)}$$

Where: VFI = Venous Filling Index (ml/s)
VV = Venous Volume (mls)
VFT = Venous Filling Time (secs)

Each patient was then asked to stand on their tip-toes using both feet for five seconds to measure the Ejection Volume (EV). They then returned to the initial position, which applied all their weight on the left leg. This movement was repeated until two of the same readings were recorded. The Ejection Volume Fraction was calculated from equation (2).

$$EVF=(EV/VV)\times 100 \quad \textbf{(2)}$$

Where: EVF = Ejection Volume Fraction (%)
EV = Ejection Volume (mls)
VV = Venous Volume (mls)

The volume of blood remaining in the veins after the volunteers did ten consecutive tip-toe movements, is known as the Residual Volume (RV). The Residual Volume Fraction (RVF) was calculated from equation (3). The patient then was asked to lie in the supine position so as to empty the veins of blood once more.

$$RVF = (RV / VV) \times 100 \quad \textbf{(3)}$$

Where: RVF = Residual Volume Fraction (%)
RV = Residual Volume (mls)

Once the veins were emptied the volunteer was asked to sit up on the bed, and place their right foot on Test Jig 1. The venous filling index was recorded again. When a steady base line was recorded the volunteer was then asked to press down the pedal of Test Jig 1 and hold it for five seconds. This procedure was repeated until two similar values were recorded. On obtaining a steady base line each volunteer was asked to press down on the pedal for ten consecutive movements. They then repeated these procedures for all four Test Jigs.

On conclusion of the fourth Test Jig, the patient returned to the supine position, and once a steady base line was reached they were asked to walk back and forth in the room for two minutes at a leisurely pace. The values of EV and RV for each volunteer were calculated as a result of walking.

The normal ejection volume fraction is greater than or equal to 60%. The normal residual volume fraction is less than or equal to 35%.

The ratios VFI, EVF and the RVF are all reproducible units irrespective of the fact that the VV may vary day to day as it is dependent on venous tone, which is variable. Therefore, Air Plethysmography was the ideal test to determine the effectiveness of the Tromped compression values, constantly producing both a sufficient EVF and RVF [30].

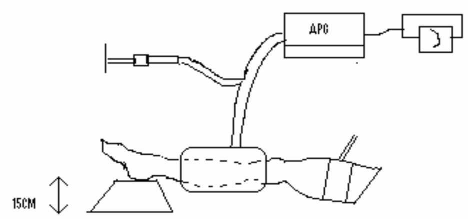

Figure 6.1. Air Plethsymograph

Figure 6.2. Medical Experiment

7.0. Conclusions

A method of preventing flight related Deep Vein Thrombosis has been developed and produced in the form of an in-flight exercise machine, called The Tromped. This machine has been produced using aircraft grade materials and practices as used in the aviation manufacturing sector. Medical and mechanical tests have shown that the device developed can prevent the occurrence of DVT by stimulating blood flow in the veins of the lower body limbs and preventing the development of thrombi. Muscle contraction is the main activator of the venous pump system, so until airlines do supply some form of prophylaxis, passengers should press the balls of their feet against the floor on a regular basis.

The commercial Tromped which will be constructed of a light weight, aircraft grade material, preferably a composite material. This will be used onboard aircraft by passengers, in compliance with aviation requirements such as Joint Aviation Requirement – Large aircraft and Federal Aviation Requirements.

If the High Courts do decide, sometime in the future that FRDVT is classified as an "accident", then airlines across the globe will have to provide some type of device to prevent passengers developing a thrombus. Otherwise they will face numerous claims for compensation, as a result of death or illness.

Devices such as Novamedix A-V Impulse System foot pump, are used on a daily basis, in hospitals, for the prevention and treatment of vascular disease. So, why not on board aircraft and other forms of transport which make long journeys? Compression Stockings have been advertised as a means of prophylaxis, for travellers for a few years now. However, to date only a very small incidence of travellers are using these items.

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